UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NORTHEASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	No. _____
v.	)	
	)	
OAKLEY PHARMACY, INC., d/b/a	)	
DALE HOLLOW PHARMACY; XPRESS	)	
PHARMACY OF CLAY COUNTY, LLC;	)	**UNDER SEAL**
THOMAS WEIR; MICHAEL GRIFFITH;	)	
JOHN POLSTON, and LARRY LARKIN,	)	
	)	
Defendants.	)	

DECLARATION OF CARL GAINOR

I, Carl Gainor, declare under penalty of perjury that the following statements are true and correct:

Professional and Academic Experience

1. I am currently an assistant professor of pharmacy at the University of Pittsburgh and have been since 1977. I am also an adjunct professor of pharmacy at two other universities: Notre Dame of Maryland University, in Baltimore, Maryland, and Belmont University in Nashville, Tennessee.

2. I am currently licensed to practice pharmacy in Pennsylvania and North Carolina.

3. I completed pre-pharmacy studies at the University of Michigan in 1963. I received my bachelor of science degree in 1966, followed by a master's degree in 1968, and a doctorate in 1972, all from the University of Pittsburgh in the study of pharmacy. I also received a law degree from the University of Pittsburgh in 1975.

4. I did a post-graduate hospital residency at the Veterans' Administration hospital system in Pittsburgh, Pennsylvania in 1967. I then practiced pharmacy as a staff pharmacist at the Montefiore Hospital in Pittsburgh, Pennsylvania from 1970 until 1976.

5. I have also practiced pharmacy as a retail pharmacist with the Thrift Drug Company in Pittsburgh, Pennsylvania, and the Kerr Drug Company in North Carolina. In addition, I worked as a part-time retail pharmacist at two independent community pharmacies in Pittsburgh, Pennsylvania.

6. As an attorney, I served as legal counsel to the Pennsylvania Pharmacists Association for approximately 25 years.

7. In my capacity as a professor of pharmacy at five schools of pharmacy over the years, I have taught thousands of students in matters of pharmacy, with an emphasis on the laws and regulations of practicing pharmacy.

8. In this capacity, I teach students the practical considerations of complying with the federal statutes and regulations pertaining to the practice of pharmacy. Chief among those statutes is the Controlled Substance Act, 21 U.S.C. § 801 *et seq.* ("CSA"), and the regulations promulgated under the CSA, particularly 21 C.F.R. Part 1300. These matters are central to the practice of pharmacy when dispensing controlled substances. I am also familiar with and teach the rules and regulations of the practice of pharmacy in Tennessee.

9. Based on my training and experience, I am specifically familiar with 21 C.F.R. § 1306.04(a), the federal regulation governing the issuance of controlled substance prescriptions, and 21 C.F.R. § 1306.06, the federal regulation that provides that a "prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a [DEA] registered pharmacy."

Materials Reviewed

10. I have been asked by attorneys from the Department of Justice to review materials provided by them with respect to two pharmacies in Celina, Tennessee: Oakley Pharmacy, Inc. which does business under the name Dale Hollow Pharmacy ("Dale Hollow"), and Clay County Xpress Pharmacy, LLC ("Xpress").

11. I have been provided with materials that I understand DEA diversion investigators acquired during an administrative inspection of Dale Hollow and Xpress as well as DEA subpoenas

concerning these pharmacies and their patients. These materials include copies of prescriptions filled by these pharmacies, the pharmacies' dispensing logs when available, information that the pharmacies kept in their patient profiles, and Tennessee Controlled Substance Monitoring Program Board of Pharmacy Patient RX History Reports ("CSMD Reports"). For each of the patients described in detail below, the materials I reviewed and relied upon are sometimes referred to as "the record."

12. The CSMD reports are compiled by an information system into which pharmacists in Tennessee are required to enter data regarding the controlled substance prescriptions they dispense to patients. This information system allows Tennessee pharmacists to review a patient's controlled substance prescription history before dispensing controlled substances. These CSMD Reports, together with the pharmacy's own dispensing logs and patient profiles, and the pharmacist's training and experience help a pharmacist determine whether a controlled substance they have been asked to dispense is for a legitimate medical purpose and from an individual practitioner (prescriber) acting in the usual course of his professional practice. For example, the pharmacists can determine which doctors have prescribed controlled substances for the patient, which pharmacies have dispensed them, the quantities and dosages that have been prescribed and dispensed, and when.

13. Armed with this information, the pharmacist can detect many red flags of diversion. For example, a pharmacist can recognize potential doctor and pharmacy shopping, combination prescriptions that might indicate abuse, dosing above the usual and customary doses, and other indication of abuse or diversion. Accordingly, the act of merely querying the CSMD report for a patient alone is insufficient. The pharmacist must evaluate the information provided in the report and apply this information to the other circumstances available to determine whether red flags of diversion are present.

Practice Standards for Retail Pharmacists

14. There are certain required steps that a Tennessee pharmacist must perform on a regular basis when filling any controlled substance prescription to ensure that the prescription is written pursuant to an appropriate physician-patient relationship, is clinically appropriate and safe to dispense. Some of the things the pharmacist should review are the patient's age, gender, current or known medical

conditions, drug allergies, the physician's address and specialty or area of practice, and the condition being treated to the extent that a diagnosis is provided. A pharmacist must evaluate the prescription for appropriateness of therapy and identify any therapeutic duplication, for instance, when more than one drug has been prescribed to treat the same condition. A prescription must also be reviewed to determine whether it satisfies all the requirements of a prescription. For instance, the prescription must contain the patient's name and address, and the physician's name and address. It should indicate the name of the drug prescribed, the strength, dosage form, quantity prescribed, and directions for use. When the prescription is for a controlled substance, it must also contain the prescriber's DEA registration number. For controlled substances, there are additional steps a pharmacist should perform to verify the legitimacy of the prescription and to prevent potential abuse and/or diversion. The pharmacist should also review the quantity of the medication prescribed; appropriate dosage; the distance of the patient's home from the physician and/or the pharmacy; trends in the physician's prescribing habits for the patient; and the number of prescribers and pharmacies the patient has used for similar medications. Schedule II controlled substances require even more scrutiny to ensure legitimacy due to the high risk of abuse and diversion. Oxycodone, morphine, hydrocodone, and other opioids are known to be commonly diverted and abused drugs in Tennessee and other states. With the rise in abuse, diversion, and drug related overdoes, such verification steps are more important than ever.

15. I am familiar with the federal requirement that a pharmacist has a "corresponding responsibility" to ensure the proper prescribing and dispensing of controlled substances (21 C.F.R. § 1306.04(a)). This is an independent responsibility of the pharmacist to ensure that prescriptions for controlled substances are legitimate. In other words, just because a licensed physician prescribed a controlled substance, does not mean that a pharmacist is obligated to fill that prescription. A reasonably prudent pharmacist in Tennessee must be familiar with suspicious activity or "red flags" indicating that the controlled substances prescribed are at risk for abuse or diversion. As a pharmacist and a professor of pharmacy, I teach pharmacy students how to detect "red flags," as well as trends in pharmacy diversion

and processes to resolve and limit any concerns that a pharmacist should have when presented with questionable prescriptions.

16. Based on my experience and available public information, opioid diversion in Tennessee and throughout the United States has increased significantly. In recent years, physicians have played a larger role in the diversion of controlled substances, either intentionally, or by failing to ensure that the prescriptions they issue are for legitimate medical purposes and issued in the usual course of professional practice.

17. As a pharmacist and a professor of pharmacy, I have been trained to recognize various red flags for abuse and/or diversion in prescriptions for controlled substances, and I teach students to do so. All competent pharmacists can and should be able to recognize "red flags" related to prescriptions for controlled substances, and they are required to do so in the usual course of pharmacy practice in Tennessee and throughout the United States.

18. Generally, a "red flag" is anything about a controlled substance prescription that would cause the pharmacist to be concerned that the prescription was not issued for a legitimate medical purpose by a registered prescriber in the usual course of professional practice. Some of the red flags for diversion that all pharmacists should be familiar with include the following:

a. The patient's address is a significant distance from the prescriber's address and/or the pharmacy's address.

b. The prescriptions are for high dosage strengths of the drug and/or for large quantities.

c. Multiple people, all of whom obtained similar prescriptions from the same physician and/or same clinic, arrive at the pharmacy at approximately the same time to have their prescriptions filled.

d. Patients are willing to pay large sums of cash (or write checks or use credit cards) for controlled substances, especially when the patients have insurance coverage available for the drugs.

e. When prescriptions are part of a prescription "cocktail." A prescription cocktail is usually a prescription for an opioid, such as oxycodone, combined with a prescription for a benzodiazepine (anti-anxiety drug) such as alprazolam (also known by its brand name, Xanax), and possibly a muscle relaxant, such as carisoprodol (also known by its brand name, Soma). Cocktail combinations are often sought by drug abusers because they produce an intensified "high," but they can be particularly deadly. The combination of an opioid, benzodiazepine, and muscle relaxant is sometimes referred to as a "Trinity" cocktail.

f. Two or more controlled substance prescriptions are issued together which indicate duplicate therapy, for example, when a patient is issued two or more prescriptions known to treat the same condition in the same manner.

19. When confronted with one or multiple red flags concerning a prescription for controlled substances, a pharmacist must intervene and resolve the red flags to determine whether or not the prescription is for a legitimate purpose *before* filling the prescription. The pharmacist must also document his or her findings for future use and reference.

20. Depending on the type of red flag, there are different steps that the pharmacist can take to determine whether or not the prescription is for a legitimate medical purpose. These steps involve obtaining more information from the physician, the patient, or both. For example, in situations where a customer from out of town is attempting to fill a controlled substance prescription, a pharmacist should seek information from the patient as to why he or she is in the area trying to fill the prescription at this pharmacy.

21. When a pharmacist contacts a physician to address red flags presented by the prescription, the standard practice is for the pharmacist to document that contact and the information the pharmacist learns. Documentation noting the red flag and how the pharmacist handled it is required. This ensures that the information is available for other pharmacy staff in the future. Documentation is required even in a pharmacy with only one pharmacist because perfect recall of every encounter with every patient is not realistic. If there is no documentation detailing how the pharmacist addressed the red

flag, then it is fair to assume that the red flag was not resolved. For example, if a conversation with the physician about the patient or the drug is not noted on the prescription or in the patient's profile, then it is safe to assume that conversation did not happen.

22. There are some red flags that a pharmacist cannot resolve by contacting the physician, obtaining a CSMD report, or obtaining more information from the patient, such as those cases when the pharmacist has reason to believe that the physician is complicit in abuse or diversion of the controlled substance.

23. As a general matter, when red flags remain unresolved, a reasonable pharmacist exercising his or her corresponding responsibility should not dispense the controlled substance prescription.

Opinions Regarding Dale Hollow Pharmacy

24. I reviewed a significant number of prescriptions for various patients of Dale Hollow Pharmacy that, based on my education, experience and expertise, raised significant red flags that the pharmacists failed to resolve. The pharmacists at Dale Hollow should not have filled these prescriptions without obtaining information that satisfactorily resolved those red flags and without documenting their resolution. It is my professional opinion that Dale Hollow pharmacists John Polston, Larry Larkin and William Lee Cole filled these prescription in violation of their corresponding duty and outside of usual course of the professional practice of pharmacy.

25. With regard to Patient B, I reviewed the CSMD report for the time period January 20, 2015 to December 10, 2018. I also reviewed 44 copies of controlled substance prescriptions for Patient B from Dale Hollow Pharmacy. These prescriptions were for the period of January 12, 2017 to June 15, 2018. Based on my review of this data I noticed numerous red flags that would indicate to a reasonable practicing pharmacist the possibility that the drugs were not being used for a legitimate medical purpose. Dale Hollow pharmacists John Polston and Larry Larkin filled controlled substance prescriptions for Patient B on an approximately monthly basis from January 2017 until as recently as June 2018. These pharmacists routinely filled prescriptions for 120 tablets of oxycodone 15 mg, 60 tablets of morphine 60

mg, and 90 tablets of alprazolam 2 mg. The combination of opioids, such as oxycodone and morphine, and benzodiazepines, such as alprazolam, is a red flag for possible abuse because it enhances the "high" experienced by those using opioid. It is also quite dangerous because it increases the respiratory depressant effect of opioids. These prescriptions also reflect unusually high dosage levels of opioids. In addition, these Dale Hollow pharmacists filled prescriptions for morphine with increasing dosages up to 100 mg per tablet from July 2017 through March 2018. It should also be noted that traveled excessive distances to obtain and fill his prescriptions. He traveled approximately 37 miles west of his home in Cookville, Tennessee, to Carthage, Tennessee, to obtain prescriptions for morphine and oxycodone. Patient B also traveled 80 miles southwest of his home to obtain prescriptions for alprazolam from a different provider than the one issuing the opioid prescriptions. Patient B would then have the prescriptions filled at Dale Hollow in Celina, Tennessee, which is approximately 36 miles north of his home. Additionally, he had an unusually long duration of opioid therapy without an adequate explanation or justification. The CSMD report also reflects that Patient B visited nine different prescribers and five different pharmacies between 2015 and 2018, raising the suspicion of doctor and pharmacy shopping to obtain his prescriptions and fill them. Based upon these facts, it is my opinion that the pharmacists could and should have noted the long duration, excessive dose opioid therapy, the simultaneous benzodiazepine therapy, the distances the patient traveled, the multiple prescribers and pharmacies utilized, and should have intervened to assure a satisfactory explanation existed to verify that these prescriptions were for a legitimate medical purpose. The record does not disclose sufficient investigation or intervention by the pharmacists. Under these circumstances, it is my professional opinion that the conduct of the pharmacists deviated from the accepted standards of the professional practice of pharmacy.

26. Dale Hollow pharmacists John Polston and Larry Larkin filled controlled substance prescriptions for Patient H on an approximately monthly basis from at least July 2016 to November 2016, and then again from December 2017 through at least June 2018. Beginning at least by July 2016 until November 2016, Patient H routinely filled prescriptions for fentanyl patches 100 mcg/hr and 120 tablets of oxycodone 10 mg at Dale Hollow. Then, beginning in December of 2017, Dale Hollow Pharmacy

pharmacists resumed filling prescriptions for oxycodone at a significantly increased dosage and quantity. The prescriptions from December 2017 through June of 2018 were for 150 tablets of oxycodone 30 mg. From July 2016 through June 2018 the pharmacists also provided Patient H with clonazepam, a benzodiazepine, on a monthly basis. Additionally, on April 20, 2018, John Polston filled a prescription for 150 tablets of oxycodone 30 mg despite the fact that the prescription was not signed, thereby rendering the prescription facially invalid. Based upon all of these facts, it is my opinion that pharmacists Polston and Larkin could and should have noted the long duration, excessive-dose opioid therapy, and the additional risk posed by the simultaneous benzodiazepine therapy; and they should have intervened to assure a satisfactory explanation existed to verify that these prescriptions were for a legitimate medical purpose. The record does not disclose sufficient investigation or intervention. Under these circumstances, it is my professional opinion that the conduct of the pharmacists deviated from the accepted standards of the professional practice of pharmacy.

27. Dale Hollow pharmacists John Polston, Larry Larkin, and others filled controlled substance prescriptions for Patient I on an approximately monthly basis from July 2016 through June 2018. During this period Patient I received prescriptions for 60 tablets of oxycodone 10 mg, 60 tablets of oxycontin 30 mg, 120 tablets of the benzodiazepine alprazolam 1 mg, 30 tablets of zolpidem (Ambien) 10 mg, and 30 tablets of phentermine 37.5 mg. It is my opinion that the pharmacists Polston and Larkin could and should have noted red flags with these prescriptions. Patient I was receiving opioids, benzodiazepines, and stimulants on a simultaneous basis, a potential warning sign for drug abuse. Patient I was also receiving both oxycontin and oxycodone at the same time for over a year, raising a question as to the legitimate need for both drugs to continue treating breakthrough pain for an extended duration. Patient I also had prescriptions filled at four different pharmacies, indicating the possibility of pharmacy shopping. Lastly, the only diagnosis indicated was degenerative joint disease/lumbar spine, an insufficient diagnosis to justify the extended opioid therapy. The pharmacists should have intervened to assure a satisfactory explanation existed to verify that these prescriptions were for a legitimate medical purpose. The record does not disclose sufficient investigation or intervention by the pharmacists. Under

these circumstances, it is my professional opinion that the conduct of the pharmacists Polston and Larkin deviated from the accepted standards of the professional practice of pharmacy.

28. Dale Hollow pharmacists John Polston and Larry Larkin filled controlled substance prescriptions for Patient J from at least March 22, 2017, through July 2018. These prescriptions included the following: 10 tablets of oxycodone (Percocet) 5 mg on March 22, 2017; 90 tablets of oxycodone 10 mg on April 4, 2017; 90 tablets of oxycodone 15 mg on May 2, 2017; 90 tablets of hydrocodone 10 mg on June 14, 2017; 90 tablets of oxycodone 10 mg on July 1, 2017; 90 tablets of oxycodone 10 mg on August 2017; 30 tablets of oxycodone 10 mg on August 28, 2017; 18 tablets of buprenorphine (Subutex) 8 mg on September 2, 2017; 8 tablets of buprenorphine 8 mg on April 14, 2018; 30 tablets of oxycodone 5 mg on May 18, 2018; 60 tablets of oxycodone 5 mg on May 29, 2018; 40 tablets of oxycodone 7.5 mg on June 14, 2018; and 30 tablets of oxycodone 7.5 mg on June 22, 2018. During this period the pharmacists should have noted various red flags of abuse or diversion. First, the pharmacists at Dale Hollow, including Polston and Larkin, should and could have noted concerns regarding the prescription history of Patient J on the CSMD Report. That report discloses that the patient, during 2015 and 2016, was obtaining prescriptions for oxycodone, morphine, hydrocodone, alprazolam, and the muscle relaxant carisoprodol. The Trinity combination of opioids, benzodiazepines, and muscle relaxants present a classic indication of abuse that is particularly dangerous. In spite of this history, the pharmacists at Dale Hollow provided additional oxycodone and alprazolam. They also dispensed Patient J buprenorphine in the formulation that does not contain the abuse deterrent naloxone without noting any reason why the patient could not tolerate naloxone. Additionally, a review of the CSMD Report for Patient J would have shown that Patient J was using a total of ten pharmacies, including both Dale Hollow and Xpress, to fill controlled substance prescriptions from more than 20 prescribers, raising the issue of doctor and pharmacy shopping. Moreover, the diagnoses given by the prescribers on the hard copy prescriptions were vague and did not sufficiently justify the controlled substances that were prescribed, absent further investigation. These diagnoses included, for example, “anxiety,” “acute low back pain,” and “chronic pain.” These diagnoses would ordinarily not justify opioid therapy spanning over two years without

further investigation by the pharmacists. The pharmacists should also have been troubled by the prescribing of oxycodone following the patient's use of buprenorphine, a drug generally used for opioid abuse-disorder. Pharmacists Polston and Larkin should have intervened to assure a satisfactory explanation existed to verify that these prescriptions were for a legitimate medical purpose. The record does not disclose sufficient investigation or intervention by the pharmacists. Under these circumstances, it is my professional opinion that the conduct of these pharmacists deviated from the accepted standards of the professional practice of pharmacy.

29. Dale Hollow pharmacists John Polston, Larry Larkin, and William Lee Cole filled controlled substance prescriptions for Patient C from July 2016 through July 2018. During this period Patient C regularly received prescriptions for oxycodone, alprazolam and carisoprodol concomitantly. This Trinity combination of drugs is a classic indication of possible drug abuse and a particularly dangerous combination. An additional red flag is that the oxycodone was increasing from 10 mg to 15 mg. The pharmacists should have intervened to assure a satisfactory explanation existed to verify that these prescriptions were for a legitimate medical purpose. The record does not disclose sufficient investigation or intervention by the pharmacists. Under these circumstances, it is my professional opinion that the conduct of the pharmacists deviated from the accepted standards of the professional practice of pharmacy.

30. Dale Hollow pharmacists John Polston, Larry Larkin, and William Lee Cole filled controlled substance prescriptions for Patient A from July 2016 through July 2018. A review of the CSMD report for Patient A indicates that, since January 2015, Patient A had been receiving monthly prescriptions for 150 tablets of methadone 10 mg, and 90 tablets of clonazepam 1 mg. Clonazepam is a benzodiazepine. The concomitant use of opioids and benzodiazepines poses a significant risk to patients suffering from respiratory problems. That is because opioids and benzodiazepines can both cause respiratory depression. In fact, the package insert for clonazepam includes an FDA-required "black box" warning addressing this very issue. In addition, the high methadone dosing for Patient A resulted in a dangerously high opioid load. Patient A was already receiving medication typically used for respiratory

difficulty, Spiriva, which should have further concerned the pharmacists. Given all of Patient A's history and drug therapy, pharmacists at Dale Hollow, including Polston and Larkin, should have intervened to assure a satisfactory explanation existed to verify that these prescriptions were appropriate and for a legitimate medical purpose. The record does not disclose sufficient investigation or intervention by the pharmacists. Under these circumstances, it is my professional opinion that the conduct of the pharmacists deviated from the accepted standards of the professional practice of pharmacy.

31. Dale Hollow pharmacists John Polston, Larry Larkin, and William Lee Cole filled controlled substance prescriptions for Patient K from July 2016 through April 2018. Almost every prescription they filled was for a controlled substance. These prescriptions included the following monthly prescriptions: 84 tablets of extended release morphine sulfate 100 mg; 84 tablets of oxycodone 30 mg (the maximum strength available); 28 tablets of oxycodone 10 mg; 84 tablets of carisoprodol 350 mg. Additionally, starting in January 2017 and through December 2017, Dale Hollow pharmacists began filling prescriptions for benzodiazepines. This addition completed the very dangerous Trinity combination frequently associated with drug abuse and diversion. The opioid therapy dose dispensed to Patient K was also dangerously high. Moreover, according to the Dale Hollow Pharmacy dispensing report, Patient K paid over $9,000 in cash for these controlled substances during the period of July 2016 through April 2018. Patient K also traveled approximately 150 miles west of his home in Livingston, Tennessee, to his prescriber in Clarksville, Tennessee. Given all these facts relative to Patient K, the pharmacists at Dale Hollow, specifically including Polston and Larkin, should have intervened to assure a satisfactory explanation existed to verify that these prescriptions were appropriate and for a legitimate medical purpose. The record does not disclose sufficient investigation or intervention by the pharmacists. Under these circumstances, it is my professional opinion that the conduct of pharmacists Polston and Larkin deviated from the accepted standards of the professional practice of pharmacy.

Opinions Regarding Xpress Pharmacy

32. I reviewed a significant number of prescriptions for various patients of Xpress Pharmacy that, based on my education, experience and expertise, raised significant red flags that the pharmacists failed to resolve. The pharmacists at Xpress should not have filled these prescriptions without obtaining information that satisfactorily resolved those red flags, and without documenting their resolution. It is my professional opinion that Xpress pharmacists Michael Griffith and Larry Larkin filled these prescription in violation of their corresponding duty and outside of usual course of the professional practice of pharmacy.

33. Xpress pharmacists Michael Griffith and Larry Larkin filled controlled substance prescriptions for Patient E from January 2015 through December 2016. These prescriptions included monthly prescriptions of either 90 or150 tablets of alprazolam 1 mg or 0.5 mg. The prescriptions also included monthly prescriptions of 90 tablets of hydrocodone (also known by its brand name Vicodin) 5 to 10 mg, and 30 to 90 tablets of oxycodone 5 mg (except for a six month period between December 2015 and mid-May 2016). During the two year period that the pharmacy provided prescriptions to Patient E, every one of the prescriptions was for a controlled substance, those being opioids or benzodiazepines, a dangerous combination drug therapy and an indication of possible drug abuse or diversion. The pharmacists should have intervened and documented legitimate explanations for two years of continuous opioid and benzodiazepine therapy. Given these facts relative to Patient E, pharmacists Griffith and Larkin should have intervened to assure a satisfactory explanation existed to verify that these prescriptions were appropriate and for a legitimate medical purpose. The record does not disclose sufficient investigation or intervention by Griffith or Larkin. Under these circumstances, it is my professional opinion that the conduct of pharmacists Griffith and Larkin deviated from the accepted standards of the professional practice of pharmacy. In this case, this 46 year-old patient met a tragic death, with the immediate cause of death being listed by the Tennessee Department of Health as “acute combined drug toxicity (alprazolam, oxycodone).” These are the very drugs the pharmacy was dispensing to Patient E. The pharmacy provided 90 tablets of oxycodone 5 mg on November 22, 2016,

and 90 tablets of alprazolam 1 mg on December 3, 2016, just six days before Patient E's death on December 9, 2016.

34. Xpress pharmacists Michael Griffith and Larry Larkin filled controlled substance prescriptions for Patient F from March 2016 through February 2017. These prescriptions included numerous controlled substance prescriptions including oxycodone between 7.5 and 20 mg tablets, alprazolam 1 mg tablets, carisoprodol 350 mg tablets, and zolpidem (Ambien) 10 mg tablets. Patient F was also receiving gabapentin (Neurontin) 400 mg capsules. Gabapentin is not currently listed as a federally controlled substance but is now listed as a controlled substance under Tennessee law. Patient F was being treated by seven different prescribers, heightening the need for the pharmacists to be alert to potential contraindicated drug therapy in addition to the risk of abuse or diversion. Additionally, the pharmacists should have noted the dangerous drug cocktail of an opioid, benzodiazepine, and muscle relaxant (together, the Trinity), with the addition in this case of a sedative/hypnotic (Ambien) and gabapentin. These additional drugs further increase the risk of harm to the patient. Given all these facts relative to Patient F, pharmacists Griffith and Larkin should have intervened to assure a satisfactory explanation existed to verify that these prescriptions were appropriate and for a legitimate medical purpose. The record does not disclose sufficient investigation or intervention by Griffith or Larkin. Under these circumstances, it is my professional opinion that the conduct of these pharmacists deviated from the accepted standards of the professional practice of pharmacy. Tragically, Patient F died on February 16, 2017, two weeks after receiving oxycodone and carisoprodol and six days after receiving gabapentin, all from pharmacist Michael Griffith at Xpress.

35. Xpress pharmacists Michael Griffith, Larry Larkin, and occasionally others, filled controlled substance prescriptions for Patient D from January 2015 through August 2018. I have been advised that Patient D is a minority owner of Xpress and a pharmacy technician there. Patient D's prescriptions included: 120 tablets of Endocet 10 mg, the brand name for oxycodone, prescriptions for between 30 and 120 tablets of oxycodone 5 mg (the generic product), six ounce bottles of hydrocodone syrup, 60 tablets of clonazepam 0.5 mg, between 30 and 90 tablets of carisoprodol 350 mg, 60 tablets of

amphetamine 10 mg (in April 2015 and September 2015) and 30 tablets of phentermine 37.5 mg (in February 2017). The prescriptions for Patient D should have alerted the pharmacists at Xpress that the patient was receiving opioids, benzodiazepines, and muscle relaxants, the dangerous Trinity combination, in addition to several prescriptions for stimulants. Additionally, Patient D appears to have requested the brand name Endocet for the 10 mg oxycodone despite its significantly higher expense, yet was satisfied with the generic version of oxycodone in the 5 mg dose. This raises a red flag because the brand name version Endocet is known to command a higher street demand and value than the generic product, especially for the higher dose version of the drug. Moreover, Patient D always paid cash for the Endocet although it appeared that Patient D had prescription drug insurance coverage. It is also of unique interest that Patient O, who lives at the same address as Patient D and appears to be Patient D's husband, is also receiving prescriptions for Endocet 10 mg tablets (from September 2015 through July 2018). Each of these prescriptions was for 120 tablets, and Patient O, just like his wife, also received the brand name product without any explanation of why the generic would not be satisfactory. Similarly, Patient P, who also lives as the same address as Patient D and appears to be Patient D's son, was also receiving monthly prescriptions of Endocet 10 mg (from December 2016 through September 2017) with quantities from 56 to 150 tablets. Again there was no explanation for why the generic version of the drug would not be acceptable. Patient P also received prescriptions for 180 capsules of gabapentin in doses ranging from 100 to 400 mg (from December 2016 through April 2018). Given these facts relative to Patients D, O, and P, apparent family members, Michael Griffith and Larry Larkin should have intervened to assure a satisfactory explanation existed to verify that their prescriptions were appropriate and for a legitimate medical purpose. Likewise, these pharmacists apparently failed to justify the patients' insistence on brand name Endocet when the generic was permitted and available. The record does not disclose sufficient investigation or intervention by the pharmacists. Under these circumstances, it is my professional opinion that the conduct of pharmacists Griffith and Larkin deviated from the accepted standards of the professional practice of pharmacy.

36. Xpress pharmacists Michael Griffith and Larry Larkin filled controlled substance prescriptions for Patients L and M who share the same address and appear to be related, from approximately February 2016 through May 2018. Both patients initially received prescriptions for 90 tablets of oxycodone 30 mg, and both patients continued to receive oxycodone on a monthly basis through July 2018. Patient L was receiving 30 mg oxycodone during the entire period, while Patient M began receiving 20 mg tablets but with an increased quantity of 120 tablets per month beginning in May 2016. Both patients displayed an alarmingly similar pattern when they received monthly prescriptions for morphine. With disturbing regularity, the patients received these prescriptions from the same doctors and had them filled by Griffith and Larkin at Xpress on the same dates. The only differences in the patients' therapies was that Patient L received almost exclusively 60 mg morphine tablets while Patient M received 15 mg and 30 mg morphine tablets. It is highly suspect for two members of the same household, separated in age by 26 years, to legitimately require almost indistinguishable, high-potency opioid drug therapy. Exacerbating this situation is the fact that each patient used the same four prescribers to obtain all of these identical drugs. Additional red flags should have been noted by Griffith and Larkin, such as the extensive distances driven by the patients, particularly since the only prescriptions these patients filled at Clay County Xpress were Schedule II opioids. Even using the most efficient routing, these patients chose to drive at least 202 miles to obtain and fill these prescriptions. Moreover, the pharmacists should have been aware of the unusually high opioid doses both patients were receiving because they themselves filled the prescriptions. The final red flag that should have been noted is that Patient M paid for all of his opioid prescriptions in cash during the period January 2016 through July 2018, paying over $8,000 for these drugs. Given all these facts relative to Patients M and L, pharmacists Griffith and Larkin should have intervened to assure a satisfactory explanation existed to verify that these prescriptions were appropriate and for a legitimate medical purpose. The record does not disclose sufficient investigation or intervention by these pharmacists. Under these circumstances, it is my professional opinion that the conduct of Michael Griffith and Larry Larkin deviated from the accepted standards of the professional practice of pharmacy.

37. Xpress pharmacists Michael Griffith and Larry Larkin filled controlled substance prescriptions for Patient N from August 2016 through August 2017. These prescriptions included hydrocodone (in strengths ranging from 5 mg to 10 mg and quantities ranging from 15 to 120 tablets), oxycodone (in strengths of 5 mg and 10 mg and quantities ranging from 20 to 120 tablets), and Suboxone (in strengths ranging from 8/2 mg to 4.2./0.7 mg and quantities ranging from 3 to 14 tablets). Significantly, Patient N was only on Suboxone therapy for a two-month period, and then inexplicably was prescribed more oxycodone. Patient N was also prescribed the sedative/hypnotic zolpidem (Ambien) 10 mg from August 2016 through September 2017 in quantities ranging from 14 to 30 tablets. Additionally, the pharmacists should have noted that this patient had nine different doctors in a single year prescribing her opioids . Given all these facts relative to Patient N, pharmacists Griffith and Larkin should have intervened to assure a satisfactory explanation existed to verify that these prescriptions were appropriate and for a legitimate medical purpose. The record does not disclose sufficient investigation or intervention by these pharmacists. Under these circumstances, it is my professional opinion that the conduct of Michael Griffith and Larry Larkin deviated from the accepted standards of the professional practice of pharmacy.

38. Xpress pharmacists Michael Griffith and Larry Larkin filled controlled substance prescriptions for Patient G from November 2015 through August 2018. These prescriptions included monthly prescriptions of oxycodone 10 mg (in quantities ranging from 40 to predominantly 120 tablets), morphine 15 mg tablets, and the benzodiazepine alprazolam 2 mg, which is the highest dose available for this drug. Patient G received prescriptions for oxycodone from eight different prescribers during this period; she received prescriptions for morphine from four different prescribers during this period; and she received prescriptions for alprazolam from four different prescribers. These facts raise a concern about the overlapping use of two powerful opioids, a concern about the dangerous combination of opioids and a benzodiazepine, and doctor shopping. Given these facts relative to Patient G, pharmacists Griffith and Larkin should have intervened to assure a satisfactory explanation existed to verify that these prescriptions were appropriate and for a legitimate

medical purpose. The record does not disclose sufficient investigation or intervention by these pharmacists. Under these circumstances, it is my professional opinion that the conduct of Michael Griffith and Larry Larkin deviated from the accepted standards of the professional practice of pharmacy.

Executed on February 5th, 2019

Carl Gainor, Ph.D., J.D.